IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: WAVE 8 CASES ON ATTACHED EXHIBIT A	

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION
TO EXCLUDE CERTAIN OPINIONS OF DR. OZ HARMANLI

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude certain opinions and testimony of Defendants' gynecology expert, Oz Harmanli, M.D. ("Dr. Harmanli"). In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Harmanli is board certified in Female Pelvic Medicine and Reconstructive Surgery. (Exhibit G, Harmanli CV, p. 3). Plaintiffs do not challenge his qualifications as such. However, Dr. Harmanli seeks to offer testimony that is not helpful for the jury, clearly exceeds the bounds of his qualifications, and is founded on insufficient facts and unreliable methodology.[1] Specifically, this Court should exclude Dr. Harmanli's opinions regarding: (1) the adequacy of Defendants' product warnings and IFUs, including opinions regarding what risks of the devices are "well known" to other doctors; (2) whether Defendants' transvaginal mesh products are defectively or reasonably designed; (3) any opinion regarding clinical differences between the mechanically cut and laser cut TVT mesh; (4) any opinion regarding safety or efficacy of the

[1] *See Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.).

mesh products observed in his own practice; and (5) the degradation of polypropylene or its clinical significance.

LEGAL STANDARD

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. Opinion evidence may be admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. In the end, an expert's testimony is admissible if it "rests on a reliable foundation and is relevant." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

The duty rests with Dr. Harmanli to proffer expert testimony and "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Even if Dr. Harmanli is qualified and his testimony is reliable, "testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15,2014) *reconsideration denied*, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, his

testimony must "fit" the case, and there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id*.

ARGUMENT

1. Dr. Harmanli's opinions on the adequacy of defendants' warnings and what other doctors know about the risks of pelvic mesh devices should be precluded pursuant to *Daubert.*

Dr. Oz Harmanli's testimony is unreliable, as he admits his opinions on the adequacy of Defendants' warnings are based on nothing more than personal convictions regarding what risks are commonly known to physicians about the device. Thus, they are *ipxe dixit* and precluded under *Daubert*. Dr. Harmanli has no independent knowledge of FDA requirements and no knowledge of industry standards regarding product warnings. He admits that he performed no independent research at all on standards of any kind before publishing his expert report. Finally, he attempts to shoehorn into evidence the same type of testimony by providing impermissible, speculative testimony as to the state of mind of other surgeons regarding what risks of the TVT he believes are "well known" to those surgeons, while admitting he has not used any reliable methodology in arriving at that conclusion. He has in fact, stated that he does not intend to offer an opinion that the warnings in the TVT IFU are adequate, merely that they are "consistent with the regulations." Such testimony lies at the heart of what *Daubert* and its progeny have found inadmissible.

This Court is obliged to exercise a "gatekeeping" function to ensure that expert testimony is both relevant and reliable. FED. R. EVID. 702; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) (*citing Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). This obligation applies to all types of expert testimony, not merely scientific analysis. *Kumho Tire*, 526 U.S. at 149; *Holsesapple v. Barrett*, No. 00-1537, 2001 WL 208490, at *1 (4th Cir. 2001).

The proponent of the testimony has the burden of proving both relevance and reliability. *Bickel v. Pfizer, Inc.*, 431 F. Supp. 2d, 918, 921 (N.D. Ind. 2006). While an expert who is a urologist or pelvic floor surgeon may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should, or should not, be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Dr. Harmanli does not possess the additional expertise to offer expert testimony about what an IFU should include, and his testimony regarding these issues should be excluded

Dr. Harmanli states that he relies on 21 CFR 801.109(c), and on his personal convictions regarding what risks are generally known to surgeons, for his opinion that the TVT mesh IFU's are adequate from a clinical and regulatory standpoint. (Exhibit B, Harmanli TVT and TVT-O expert report, p. 14). However, Dr. Harmanli admits he does not hold any regulatory certificates, had not had any formal education or training in that area, and has never served as an expert in interpreting statutes and regulations.

> Q. Do you hold any regulatory certifications or belong to any regulatory societies?
>
> A. I do not.
>
> Q. Have you had any formal education or training in that area?
>
> A. **I don't think anyone needs it.** Just read the code, be a doctor, you'll understand it better than anybody else.
>
> ***
>
> Q. Have you ever served as an expert in that area, interpretation of statutes or regulations?
>
> A. I don't remember. [2]

[2] Dr. Harmanli Dep. Tr., 10-03-2018 Vol. 1. 64:17-24, 65:4-6; Plaintiff's Motion, Exhibit C.

Dr. Harmanli did not obtain the specific CFR section he relies upon through his own independent research, but rather, it was provided by "his discussions and readings with the Ethicon material."[3] In addition, Dr. Harmanli appears to be creating his own standard(s) for what information needs to be included in the IFU, one that concludes that a medical device manufacturer must only comply with regulations:

> Q. Can you tell me what risk information medical companies are required to put in their IFUs or instructions for use?
>
> A. So you know, as you know, there are federal and state rules, right, regulations. So I want to come up with a new medical device, I got to FDA. Whatever FDA says, I must fulfill. So FDA tells them to put in information on the IFU, they go do that. So that's what I pay attention to. So if they obey FDA rules in whatever product they're marketing in any state and following those state rules as well, then they fulfilled their obligations.[4]
>
> ***
>
> Q. So It's your opinion that if the FDA clears the device and the labeling included with that device, that that's – they met the requirements and that's all they have to do?
>
> A. **That's good enough for me. …**[5]
>
> ***
>
> Q. Have you ever served as an expert in that area, interpretation of statutes or regulations?
>
> A. I don't remember. [6]

In fact, Dr. Harmanli has admitted in his testimony that does not intend to offer an opinion in this case that the IFU is adequate to warn physicians about the risks of the device, he only has an opinion that the IFU is consistent with the regulations:

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[3] *Id.* at 63:22-25.
[4] *Id.* at 52:25-53:11
[5] *Id.* at 60:8-12
[6] *Id.* at 65:4-6

> Q. So, Doctor, I assume that you intend to offer an opinion in this case that the TVT and TVT-O IFUs, or Instructions For Use, are adequate to warn physicians about the risks of the device, right?
>
> A. That is also wrong. **That is consistent with the regulation. That is all I'm saying**[7]
>
> ***
>
> Q. You're not going to offer an opinion in this case that the warnings in the TVT and TVT-O IFU are adequate for physicians using the device?
>
> A. So let me phrase it this way. IFU, in my mind is a regulatory document. It 's between the company and the FDA. If FDA says it's okay by FDA, they meet that criteria to be able to market, launch this product here, and the rest is up to me. That's all I'm saying.
>
> **I'm not saying it's adequate.** FDA could ask them to do more. They should – then do more. Whatever FDA regulatory process requires, they must meet that. That's IFU. That's the definition of IFU.
>
> Regulatory process requires this stated in the IFU, the rest is mine. And I as a surgeon, I as a teacher, must teach my residents, fellows, and tell my patients that this is not it. There is a risk.
>
> **Whatever is written on the IFU doesn't matter. That's all I am saying**.[8]

More troubling is that Dr. Harmanli ignored the specifics of any other FDA standards which are contrary to his opinion, such as the blue book standard, which states that an appropriate warning should be included in an IFU if there is reasonable evidence of an association of a serious hazard with the use of a device, regardless of whether a causal relationship has been proven.[9] Dr. Harmanli appears to have relied solely on a single section of the Code of Federal Regulations given to him by counsel for Defendants for his opinions that the

[7] Dr. Harmanli Dep. Tr., 10-03-2018 Vol. 2. 142:1-6 Plaintiff's Motion, Exhibit D (emphasis added).
[8] *Id*. at 142-9:143:2 (emphasis added).
[9] Dr. Harmanli Dep. Tr., 10-03-2018 Vol. 1. 57:22-25 Plaintiff's Motion, Exhibit C: Dr. Harmanli states that he is familiar with the Blue Book Regulation, but did not specifically review it for this case. Dr. Harmanli states that he disagrees that the appropriate standard for a manufacturer to follow is that a manufacturer should include an appropriate warning if there is a reasonable evidence of an association of a serious hazard with the use of the device, *Id.* at 59:20-60:1. Yet, this is the very standard that the FDA's Blue Book memorandum states should be followed. See Ex. E, Blue Book Memo, Section V. (page 4/10).

TVT IFU's are "consistent with the regulation," and he has done no independent research to verify whether there are other legal standards that contradict his opinion. He also inconsistently applies the regulatory guidance, at one point disagreeing that a manufacturer should try to follow guidance documents issued by the FDA, and later stating that guidance documents can be helpful.[10] This is inconsistent with *Daubert* standards, which require an expert to apply a reliable methodology in forming their opinions. In addition, he does not have the regulatory or legal background required to interpret such a standard.

Dr. Harmanli states repeatedly in his report that the risks of the pelvic mesh devices are well-known or commonly known to physicians, [11] and uses this as part of the basis for his opinion that the IFU's are adequate. However, Dr. Harmanli has never done any kind of survey or used any kind of formal methodology to determine what physicians did or did not know with regard to the pelvic mesh devices.[12] He admits that his opinion that the risks of the TVT and TVT-O are commonly known to surgeons is not based on any formal analysis, but rather the inherent nature of pelvic surgery.[13] He cannot, for example, state what percentage of physicians knew that chronic pain could result specifically from the TVT mesh at the time of launch.[14] Since Dr. Harmanli is relying on what physicians commonly knew about the risks of the devices, yet he cannot state what percentage of physicians knew about particular risks, then he cannot reliably testify as to whether the IFU were adequate. He admits his opinion is not grounded on any objective evidence. Rather, Dr. Harmanli simply provides his own *ipse dixit* to support his opinions.

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[10] *See* Ex. C at 67:5-11, *compare with* 67:21-25
[11] Ex. B at 15, 20, 23
[12] Ex. D at 128:11-14
[13] *Id.* at 128:15-22
[14] *Id.* at 129:14-19

Dr. Harmanli's opinion that physicians knew all the risks of the pelvic mesh devices appears to be based on his personal conviction that any doctor who did not previously know about the additional risks that were added to the TVT IFU in 2015, was at fault for not having that knowledge.[15] But he has no objective evidence for this conclusion. It is purely speculation, as he has conducted no inquiry into what risks doctors who use the pelvic mesh devices actually know.[16] Dr. Harmanli's testimony on the adequacy of Defendants' warnings should be excluded because it is based on no objective criteria. Instead, it is based on Dr. Harmanli's personal belief that all surgeons have reviewed and retained information regarding specific risks of the TVT devices. Federal courts have consistently held that *ipse dixit* – opinions justified solely by the fact that the expert holds them -- are inadmissible. *See, e.g., GE v. Joiner*, 522 U.S. 136, 146 (1997); *see also Pampered Chef v. Alexanian*, 804 F. Supp. 2d 765, 794 (N.D. Ill. 2011) ("If admissibility could be established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong."). The Fourth Circuit concurs. *Holesapple*, 2001 WL 208490 at *2 ("[I]t still is a requirement that the expert opinion evidence be connected to existing data by something more than the 'it is so because I say it is so' of the expert."). This Court has also excluded *ipse dixit* opinions. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 603 (S.D.W. Va. 2013).

To be admissible, expert testimony must explain the link between the available evidence or data and the expert's opinion. *United States v. Mamah*, 332 F.3d 475, 478 (7th Cir. 2001); *see also Cunningham v. Masterwear, Inc.*, No. 1:04-cv-1616-JDT-WTL, 2007 WL 1164832, at *9 (S.D. Ind. Apr. 19, 2007) ("It is not enough for an expert to say this is my data and that is my conclusion without connecting the two."); *Mid-State Fertilizer Co. v. Exchange Nat. Bank of*

[15] *Id.* at 143:18-145:5
[16] *Id.* at 129:14-19

Chicago, 877 F.2d 1333, 1390 (7th Cir. 1989) ("An opinion has a significance proportioned to the sources that sustain it.").

Similarly, in this case, Dr. Harmanli's testimony on the IFU, by his own admission, is only that the warnings are "consistent with the regulation," not that they are adequate. This is based on a single section of the Code of Federal Regulations, which he is not qualified to interpret; he has ignored conflicting regulations and guidance; and it is supported by *ipse dixit* opinions that all physicians already know of the risks of the pelvic mesh devices. Those opinions are thus inadmissible under the *Daubert* line of cases.

II. Dr. Harmanli should be precluded from giving opinions on the design of the mesh products, including whether the devices are designed in a reasonable manner.

Dr. Harmanli should be precluded from offering any opinions regarding the design of the subject products. Specifically, he should be precluded from offering any opinions regarding whether the subject products are defectively designed; any opinions as to whether a mesh with a lighter weight/larger pore mesh with heat sealed edges would be safer or more effective; any testimony regarding the effect of helical passers on the safety of a device; and any opinions regarding the sufficiency of the defendants' risk assessments performed during the design of the products, including but not limited to the design failure modes effects analysis (dFMEA).

The most compelling reason why Dr. Harmanli should be precluded from opining about the design of the subject products is that he admits he is not aware of any standards that a mesh manufacturer must follow in designing mesh products other than "whatever the FDA says":

> Q. Do you know any standards that a medical device manufacturer must follow in designing; can you name any?
>
> A. FDA for medical devices made it clear. Just follow that.
>
> Q. So other than FDA regulations, are you aware of any standards that a mesh manufacturer must follow in designing mesh products?

A. I would go by whatever FDA says.

Q. Do you know what internal standards that Ethicon must follow in designing mesh products

A. **I don't know what internal standards are and would mean,** but as long as FDA regulations are met, I am happy with the product. [17]

This Court has previously recognized the importance of an expert's admission that he is not an expert on the relevant standards. In the *Bard* litigation, this Court precluded Dr. Shull from giving warnings opinions because he had testified that "I would not claim to be an expert in that area." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). That same analysis applies here to Dr. Harmanli, who admitted he is not an expert on standards Ethicon must follow in designing mesh products. As such, he should be precluded from giving any opinions related to design of the subject products, including whether or not the products are designed in a reasonable manner.

a. Dr. Harmanli did not review Defendants' key documents related to product design

Dr. Harmanli should also be precluded from opining about the design of the subject products because he has not reviewed Defendants' internal documents about the design process. This issue was central to the exclusion of design opinions by a urogynecologist for the plaintiffs in the Boston Scientific litigation. Boston Scientific Corp. ("BSC") moved to exclude Dr. Bob Shull because he "reached opinions on the improper design of the Uphold without having first considered BSC's design protocols." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015). The plaintiffs countered that Dr. Shull had relied on other BSC internal documents, as well as the scientific literature. *Id.*

[17] Ex. C at 68:11-24 (emphasis added).

This Court agreed with BSC and excluded Dr. Shull from giving any design opinions. This Court reasoned that "regardless of the literature he has reviewed or the experience he has gained, a necessary piece of data remains missing from Dr. Shull's methodology. Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

Dr. Harmanli also confirmed he has not read the design failure modes and effects analysis for the subject products. He also does not know what that phrase means, what the purpose is, or how that process applies in design.[18] He also has not reviewed the risk analysis for the TVT products.[19] He did not review the design history file of the TVT or TVT-O device before he issued his opinions in this case.[20] He has not reviewed any of Ethicon's internal standard operating procedures related to design.[21]

In addition to not knowing the relevant standards to apply in determining whether a medical device is reasonably designed, because he did not review the relevant design documents and has not done the appropriate risk analysis, Dr. Harmanli lacks the required knowledge and foundation to give a reliable opinion about the reasonableness of the design of Defendants' transvaginal mesh products. Based on the foregoing, all Dr. Harmanli's opinions on the issue of product design should be excluded.

[18] Ex. C at 70:24-71:21
[19] *Id.* at 70:21-23
[20] *Id.* at 69:24-70:6
[21] *Id.* at 9-11

III. Dr. Harmanli's opinion there is no clinical difference between mechanically cut versus laser cut mesh with respect to the effectiveness or safety in the medical literature is not reliable.

Dr. Harmanli seeks to testify that there is no clinical difference between mechanically cut and laser cut TVT and TVT-O in the medical literature.[22] The only two studies which Dr. Harmanli is relying on for this conclusion are the Rusavy and Thubert studies cited in his report.[23] Upon cross-examination, Dr. Harmanli admitted that the Thubert paper did not state anywhere whether the TVTs used in this study were mechanically cut or laser cut.[24] When asked how he determined that this article supports his conclusion that there is no clinical data to support the difference despite this lack of data, he answered:

> A. I was probably told by my lawyers, who provided these papers, that it was a significant paper regarding that. And that's why I use it as a – so TVT – Exact and TVT differed in how they were cut. So that's why that conclusion could be because of that.[25]

With regard to the Rusavy study, Dr. Harmanli admitted that the investigators in that study concluded that the laser cut and mechanically cut TVT-O actually do differ in terms of handling and insertion, and also in biomechanical properties such as stiffness and elasticity.[26] He further agreed that because of this difference, the investigators actually changed the way the laser-cut TVT was implanted, and this was a flaw in the study, and a bad way of reporting outcomes.[27] Dr. Harmanli agreed that the author's conclusion that there is no difference in clinical outcomes between the two mesh cutting methods is inconclusive because it is unknown whether this change the change in implantation method affected the outcome of the study:

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[22] Ex. B at 17, paragraph 2.
[23] Ex. D at 160:25-161:19
[24] *Id.* at 162:11-21
[25] *Id.* at 162:25-9
[26] *Id.* at 163:13-24
[27] *Id*. at 164:3-23

> Q. ...we don't know if that conclusion was confounded by the fact that they changed the way they were implanting the laser cut mesh, right?
>
> A. It's inconclusive regarding that.[28]

Thus, by Dr. Harmanli's own admission, the only two pieces of evidence that support his opinion are a study that counsel for Ethicon told him supported his opinion—which he then put into his report without any analysis of his own—and one that is inconclusive as to the subject of his opinion. That is simply not a reliable basis for a biomedical opinion regarding clinical outcomes of laser cut vs mechanically cut TVT. This Court has previously rejected this sort of "I have not seen it, therefore it must not happen" logic. Indeed, in ruling on *Daubert* motions in *Tyree*, the Court held that the "[a]bsence of evidence is not evidence of absence," and refused to allow defendant's expert to opine that certain events do not occur simply because he had not observed them in his practice.[29] By that same unassailable reasoning, Dr. Harmanli's admits his claim that there is no clinical difference between mechanically cut and laser cut mesh is based on only two articles, one which was only cited as it was provided by counsel, and the other he admits is inconclusive.

As this Court held in *Sanchez*: "[a]n expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.' '[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.'" [30]

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[28] *Id.* at 165:8-11
[29] *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 583-85 (S.D. W. Va. 2014)).
[30] *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 U.S. Dist. LEXIS 137189, *70 (S.D. W. Va. Sept. 29, 2014) (citations omitted).

Moreover, this type of testimony is not helpful to the jury—because it provides no scientific basis upon which the jury could rely.[31] Neither *Daubert* nor the Federal Rules of Evidence require the admission of opinion evidence that is merely *ipse dixit* of the expert, and a court may conclude that there is too large of an analytical gap between the data and the opinion proffered.[32] That is precisely the case here.

IV. Dr. Harmanli's opinions about his personal experience related to the safety and efficacy of the pelvic mesh products should be excluded because they are not based on any objective standard, and his analysis and methodology are flawed.

Dr. Harmanli should be precluded from testifying about his perceived safety and efficacy rates with the subject products from his practice, as those opinions are entirely unsupported by any reliable methodology and have not been subject to peer review. This court has already ruled that an expert cannot relate precise statistics based on their own assurances that those statistics are reliable. *In re: Ethicon, Inc.*, No. 2327, 2016 WL 4542054, at *4 (S.D.W. Va. Aug. 30, 2016).

Dr. Harmanli has stated in his expert report that he has used both mechanically cut and laser cut TVT and TVT-O, and can attest that he has not noticed any clinical difference between them with respect to effectiveness or safety his clinical practice.[33] However, in arriving at this opinion, Dr. Harmanli admits he does not know whether or not he is currently using the Ethicon laser cut mesh or the mechanically cut mesh.[34] He does not even know how to tell whether or

[31] *See generally Sandow-Pajewski v. Busch Entertainment Corp.*, 55 F. Supp. 2d 422, 427 (E.D.Va. 1999).
[32] *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).
[33] Ex. B at 17, paragraph 2.
[34] Ex. C at 20:23-21:14

not a TVT product is laser cut or mechanically cut when he pulls it off the shelf.[35] Dr. Harmanli admits that this opinion is not based on any formal analysis:

> Q. So your opinion that you haven't noticed any clinical difference between mechanically cut versus laser cut mesh with respect to effectiveness or safety isn't a result of any kind of formal analysis or study that you've done on your own patients, correct?
>
> A. That's correct.[36]

Indeed, there cannot be any formal analysis on this point, or even any reliable conclusion, as it is clear that Dr. Harmanli has no idea when he is using a mechanically cut mesh device versus when he is using a laser cut.[37] Dr. Harmanli's opinions about clinical outcomes with TVT among his own patients is inappropriate, unsupported, and inadmissible. He lacks any reliable methodology or analysis to support his conclusions. In addition, allowing Dr. Harmanli to offer an opinion as to his clinical outcomes with TVT for his own patients would be confusing and misleading to a jury when considering whether the mesh devices in question are defective. Thus, the opinion should also be excluded under Rule 403. Because there is no foundation for his opinions, Dr. Harmanli should be prohibited from providing this testimony.

V. Dr. Harmanli should be precluded from testifying that polypropylene does not degrade.

Dr. Harmanli seeks to offer the opinion that "degradation and inflammation, whether it exists or not, is not clinically significant."[38] Dr. Harmanli's opinions regarding the degradation of polypropylene mesh should be excluded.

As an initial matter, Dr. Harmanli's lack of education, training, and knowledge about the degradation process and the chemical properties of Prolene, should serve to preclude his so-

[35] *Id.* at 21:15-18
[36] Ex. D at 160:19-24
[37] *Id.* at 14-18
[38] Ex. B at 22

called "expert" opinions on the issue. For example, Dr. Harmanli has no background or training specifically in polymer chemistry.[39] He has never done any research specifically in the area of polymer chemistry.[40] He agrees that he would not hold himself out as a pathologist.[41] He has never published any opinions that polypropylene does not degrade in the human body.[42]

Moreover, Dr. Harmanli did not review necessary and relevant documents regarding degradation—including the testimony of Ethicon's designated witness on the topic of polypropylene degradation—and instead, he just insists that polypropylene mesh does not degrade:

> Q. But did you understand that in this case there's actually been a person named Thomas Faribault that was designated on behalf of the company on the issue of whether or not polypropylene degrades and that individual did offer sworn testimony under oath?
>
> A. I was not aware
>
> Q. And you didn't review that testimony in forming your opinions in this case that the mesh does not degrade, right?
>
> A. I don't remember reading that testimony. [43]

Dr Harmanli also testified that he is not sure whether there are more than 25 peer reviewed published articles that conclude that polypropylene mesh used in the pelvic floor degrades, but "whatever exists there does not seem substantial to me."[44] Dr. Harmanli chooses to ignore the relevant evidence,[45] and instead, just blindly asserts that if there are studies showing that degradation is clinically significant, they are "cancelled out" by at least two studies with 17-year

[39] Ex. C at 49:9-11
[40] *Id*. at 50:6-3-5
[41] *Id*. at 51:11-14
[42] *Id*. at 52:14-17
[43] Ex. D at 183:5-18. Note, it would appear that the court reporter incorrectly transcribed "Thomas Barbolt" as Thomas Fairbault"
[44] *Id.* at 181:12-18
[45] *See Sanchez*, 2014 U.S. Dist. LEXIS 137189, *70.

data.[46] However, an expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation.[47]

Dr. Harmanli also testified that he was not aware that the manufacturer of the raw polypropylene which goes into the TVT and TVT-O has warned that strong oxidizers, such as peroxides, are incompatible with the TVT and TVT-O.[48] Dr. Harmanli admits that he is aware that the vaginal region is a natural source of peroxides, but he has not studied the question of whether or not the peroixides in the vagina affect the composition of the TVT mesh.[49] Any claim that his degradation opinion is based upon rigorous study or reliable methods should be rejected as scientifically unsound. Similar to the opinions discussed above, Dr. Harmanli's opinion that degradation does not occur, or that it is not "clinically relevant," should be excluded because it is neither supported by his review and understanding of the scientific material, nor by scientifically reliable clinical experience.

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Harmanli is sufficiently qualified, and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in the opinions discussed above, Ethicon cannot carry this burden and his testimony should be accordingly limited.

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[46] Ex. D at 181:20-182:8

[47] *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3 (4th Cir., Sept. 8, 1997); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

[48] Ex. D at 184:12-19. *see also* Ex. F, Material Safety Data Sheet for Polypropylene used in the TVT products at page 4: "The following materials are incompatible with this product: Strong oxidizers such as ….peroxides…"

[49] Ex. D at 184:21-185

Dated: October 18, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2018, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

s/ Jeffrey M. Kuntz